



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1617

1617
TFW \$

Patent Application of

Richard B. Mazess

Application No. 09/995,911

Confirmation No.: 4126

Filed: November 28, 2001

Examiner: Leonard M. Williams

"TREATMENT OF
HYPERPROLIFERATIVE DISEASES
USING ACTIVE VITAMIN D
ANALOGUES"

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §1.97(c)

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Sir:

The Examiner's attention is directed to the references which are listed on the attached Form PTO/SB/08A and/or PTO/SB/08B and copies of non-U.S. patent references are attached. This Statement is also being accompanied by a check in payment of the \$180.00 fee required under 37 CFR §1.17(p). Please charge or credit Deposit Account No. 50-0842 with any shortage or overpayment of the required fee.

Citation of these references is respectfully requested.

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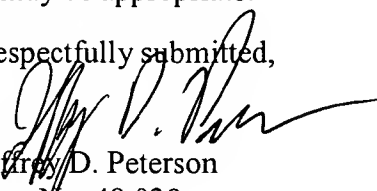
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Sandy Tabachnick
Signature

December 19, 2005
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No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,



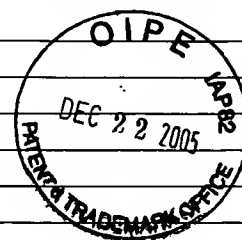
Jeffrey D. Peterson
Reg. No. 49,038

File No. 017620-9335

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| | | | | Application Number | 09/995,911 |
| | | | | Filing Date | November 28, 2001 |
| | | | | First Named Inventor | Richard B. Mazess |
| | | | | Group Art Unit | 1617 |
| | | | | Examiner Name | Leonard M. Williams |
| Sheet | 1 | of | 1 | Attorney Docket Number | 017620-9335 |



U.S. PATENT DOCUMENTS

| Examiner Initials | | U.S. Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document |
|----------------------|--|-----------------------------|---|---------------------------------------|
| | | 4,686,104 | Bockman et al. | 8/1987 |
| | | 5,264,184 | Aysta et al. | 11/1993 |
| | | 5,300,687 | Schwender | 4/1994 |
| | | 5,527,524 | Tomalia et al. | 6/1996 |
| | | 5,547,947 | Dore et al. | 8/1996 |
| | | 6,395,784 | Ryono | 5/2002 |
| | | 6,566,353 | Bishop et al. | 5/2003 |
| | | 6,573,256 | Bishop et al. | 6/2003 |
| | | 6,680,309 | Bishop et al. | 1/2004 |
| | | 2003/0207810 | Bishop | 11/2003 |
| | | 2004/0023934 | Bishop | 1/2004 |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | Country Code | Foreign Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Translation | English Abstract |
|----------------------|-----------------|-----------------------------------|--|--|-------------|---------------------|
| | WO | 90/01321 | Bone Care International, Inc. | 2/1990 | | |
| | WO | 98/29123 | Bone Care International, Inc. | 7/1998 | | |
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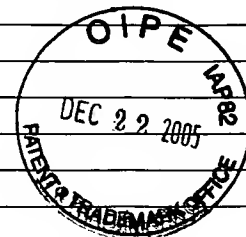
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| | | | | Examiner Name | Leonard M. Williams |
| Sheet | 1 | of | 3 | Attorney Docket Number | 017620-9335 |

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. |
|----------------------|--|--|
| | | COHEN-SOLAL, M.E., et al., "1,25 Dihydroxyvitamin D and dexamethasone decrease in vivo walker carcinoma growth, but not parathyroid hormone related protein secretion," Horm. Metab. Res. (1995) 27:403-407 |
| | | EL ABDAIMI, K. et al, "Reversal of hypercalcemia with the vitamin D analogue EB1089 in a human model of squamous cancer," Cancer Research (1999) 59:3325-3328 |
| | | EL ABDAIMI, K. et al. "Expression and regulation of parathyroid hormone-related peptide in normal and malignant melanocytes," Am. J. Physiol. Cell Physiol. (1999) 279(4):C1230-1238 |
| | | ENDO, K. et al., "1,25-dihydroxyvitamin D3 as well as its analogue OCT lower blood calcium through inhibition of bone resorption in hypercalcemic rats with continuous parathyroid hormone-related peptide infusion," J. Bone and Min. Res. (2000) 15(1):175-181 |
| | | ENDO, K. et al., "Evidence for the uptake of a vitamin D analogue (OCT) by a human carcinoma and its effect of suppressing the transcription of parathyroid hormone-related peptide in vivo," J. Biol. Chem. (1994) 269(51):32693-32699 |
| | | ESBRIT, P. et al., "Parathyroid hormone-related protein as a renal regulatory factor: from vessels to glomeruli and tubular epithelium," http://www.uninet.edu/cin2000/conferences/bosch/bosch.html |
| | | FALZON, M. and AONG, J., "The noncalcemic vitamin D analogs EB1089 and 22-oxacalcitriol suppress serum-induced parathyroid hormone-related peptide expression in a lung cancer cell line," Endocrinology (1998) 139(3):1046-1053 |
| | | Goodman and Gilman's The Pharmacological Basis of Therapeutic, 7th edition, 1573-1580 |

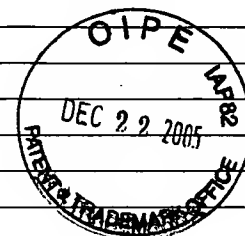
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|----------------------|--|--|
| | | HAQ, M. et al., "A vitamin D analogue (EB1089) inhibits parathyroid hormone-related peptide production and prevents the development of malignancy-associated hypercalcemia in vivo," J. Clin. Invest. (1993) 91:2416-2422 |
| | | HOLICK, M.F. et al., Science (1973) 180:190-191 |
| | | JOHNSTON, S.R. and HAMMOND, P.J., "Elevated serum parathyroid hormone related protein and 1,25-dihydroxycholecalciferol in hypercalcaemia associated with adult T-cell leukaemia-lymphoma," Postgrad Med. J. (1992) 68(803) Abstract |
| | | JONES, G. et al., Biochemistry (1975) 14:1250-1256 |
| | | KREMER, R. et al., "Reversal of hypercalcemia with the vitamin D analog EB1089 in a human model of squamous cancer," J. Bone Mineral Research, ASBMR 18th Annual Meeting (1996) 289 |
| | | LUPARELLO, C. et al., "Use of M-MLV RT, Rnase H-, point mutant for mRNA-differential display analysis of parathyroid hormone-related peptide (PTHrP) - treated breast carcinoma cells," Promega eNotes (2001) 1-7 |
| | | MANTELL, D.J. et al., "1alpha,25-dihydroxyvitamin D3 inhibits angiogenesis in vitro and in vivo," Circulation Research (2000) 214-220 |
| | | MOTELLON, J.L. et al., "Parathyroid hormone-related protein, parathyroid hormone, and vitamin D in hypercalcemia of malignancy," Clinica Chimica Acta (2000) 290:189-197 |
| | | OGATA, E., "Parathyroid hormone-related protein as a potential target for cancer-associated morbidity," Supp. Cancer (2000) 2909-2911 |

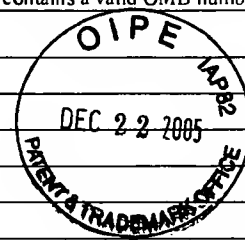
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| | | SATO, K. et al., "Increased 1,25-(OH)2D2 concentration in a patient with malignancy-associated hypercalcemia receiving intravenous hyperalimenation inadvertently supplemented with vitamin D2," Intern. Med. (1993) 32(11):886-890 |
| | | TANIGUCHI, F. et al., "Successful management of humoral hypercalcemia of malignancy in a patient with ovarian cancer," Yonago Acta Medica (2000) 43:81-86 |
| | | WIGINGTON, D.P. et al., "Combination study of 1,24(s)-dihydroxyvitamin D2 and chemotherapeutic agents on human breast and prostate cancer cell lines," Anticancer Research (2004) 24:2905-2912 |

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